Treatment of High Risk Acute Leukemia with CD40 Ligand and IL-2 Gene Modified Autologous Bone Marrow Fibroblasts And Tumor Cells

Non-Scientific Summary

We have designed a research study to determine the safety and effectiveness of gene modified cells that may make the patient's own immune system fight leukemia. We will use an adenoviral vector to put two genes into normal cells (fibroblasts) grown from the patient's own marrow. These gene modified cells will then be injected subcutaneously into the patient, together with some of the patient's own leukemia cells. The fibroblasts will contain two new genes called interleukin-2 and CD40 Ligand that we hope will make the immune system recognize leukemia cells more effectively. Initially, we hope that they will recognize the leukemia cells present at the injection site with the gene modified fibroblasts. Subsequently, we hope the immune response generated will recognize the malignant cells elsewhere in the body. This type of approach has been successful in animal models and in some clinical studies.

We will be treating patients whose leukemia has responded poorly to conventional treatment or is at high risk of coming back. We will use increasing doses of the gene modified cells and look for unexpected side effects. We anticipate treating 12-15 patients, increasing the dose of gene modified cells every fourth patient. All the cells injected will be irradiated beforehand to stop them from growing in the patient. The study will look for side effects and for evidence of anti-leukemia immunity.